

## DETAILED ACTION

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 237-264 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 183, 186-187 of copending Application No. 10/960,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker at the center of the body, where the marker can be a wire, radiopaque or echogenic. Although the present invention and the '622 application differ in that the present invention teaches that the second material comprises unitary piece of metal and the '622 application teaches a wire. The examiner

stands that one of ordinary skill in the art would recognize that similarity and interchangeability between a wire and a unitary piece of metal. Additionally, the examiner stands that the presently claimed wound suture material and the porous suture material claimed by the '622 application are both disclosed as promoting tissue ingrowths. Here, the examiner maintains that these are obvious variations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claim 237-264 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 33-34, 122-123 of copending Application No. 09/805,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a device for implanting a marker device comprising a metallic marker and a bioabsorbable or porous filler body. Because of the extent of overlapping subject matter, the Examiner stands that it would be obvious to one of ordinary skill in the art to recognize that biocompatible suture-type material with a metallic marker disposed therein would be an equivalent to the subcutaneous marking device of claim 1, for example, comprising at least two implantable bodies it would have been obvious to have provided at least two bodies. Additionally, the Examiner stands that the presently claimed wound suture material and the porous material claimed by the '652 application are both disclosed as promoting tissue ingrowths. Here, the examiner maintains that these differences between the wound material and the porous material are obvious variations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 237-264 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 104 of copending Application No. 10/114,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim substantially the same subject matter comprising a marker that comprises a bioabsorbable filler with a detectable, where the marker can be a wire, metallic, and/or radiopaque. Although the 10/114,712 application does not expressly disclose an apparatus deploying the marker, it would have been obvious to one of ordinary skill in the art who is in possession of a marker to deploy the marker using any known elongate puncture or catheter device. Additionally, the Examiner stands that the presently claimed wound suture material and the porous material claimed by the '712 application are both disclosed as promoting tissue ingrowths. Here, the examiner maintains that these differences between the wound material and the porous material are obvious variations.

5. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 237-264 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/283,310. Although the conflicting claims are not identical, they are

not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material including bioabsorbable material and a metallic material. The present invention claims an insertion device and that the marker device comprises two materials, a suture type bioabsorbable material and the '310 application claims the insertion device and a bioabsorbable matrix and a radiographically detectable second material (e.g. claims 1-4). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art. Additionally, the Examiner stands that the presently claimed wound suture material and the fibrous matrix material claimed by the '310 application are both disclosed as promoting tissue ingrowths. Here, the examiner maintains that these differences between the wound material and the porous material are obvious variations.

7. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 237-264 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11-15, 17, 26-39, 43-61, 65-80, 87, 90-102 of U.S. Patent No. 6,371,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a

bioabsorbable filler with a detectable marker that comprises metal where the bioabsorbable filler comprises a threaded material.

9. Claim 237-264 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32-33 of U.S. Patent No. 6,356,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker that comprises metal. Additionally, the Examiner stands that the presently claimed wound suture material and the fibrous matrix material claimed by the '782 patent are both disclosed as promoting tissue ingrowths. Here, the examiner maintains that these differences between the wound material and the porous material are obvious variations.

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 237-264 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burney et al. (USPN 6,056,700) in view of Preissman (USPN 6,309,420).

12. Regarding claims 237-240, 242-243, 244-247, 249-264, Burney discloses an elongate member having a distal portion and a proximal portion with a lumen having internal walls (13) extending between the distal and proximal portions (See Figs. 1-5), said distal portion configured to seat the marking device in contact with the internal walls and advance the marking device within the distal portion to the target side (See Figs 1-7, 9-11, 13-14 & 27); an ejector coupled to the elongate portion, the ejector configured to disengage the marking device from the distal portion (col. 5, ll. 45-53; See Fig. 26); a marking device preloaded in the elongate member distal portion, for delivery through the lumen (Figs. 9-10, 13-14); wherein the marking device comprises a first component comprising a wound arrangement having multiple passes of the material forming a loosely wound ball body (col. 7, ll. 22-24; Fig. 17) comprising bioabsorbable material (col. 6, ll. 43-46). Burney also discloses that the preferred materials will be flexible enough to be compressed or bent into a spring loaded state into the cavity and resilient enough to expand when delivered from the delivery device to the target site (col. 7, ll. 1-5).

13. Regarding claim 254, Burney discloses that the first component is echogenic (col. 6, ll. 31-33).

14. Regarding claim 257, the Examiner stands that the disclosed "loosly wound ball of string" would inherently be configured to allow tissue to regrow from one side of the body through to the other side.

15. Burney does not explicitly disclose that the wound arrangement comprises bioabsorbable suture material that carries a unitary piece of metal. Burney also does not

explicitly disclose that the body comprises a material selected from the group set forth by claim 259.

16. In a related field of endeavor, Preissman discloses an enhanced visibility composition for implantation from a remote source so that the composition can be readily observed under fluoroscopy (Abstract). Preissman goes on disclosing that a matrix material may comprise known flexible and bioabsorbable suture material (col. 6, II. 1-18: Here the Examiner stands that various forms and states of bioabsorbable materials are known to include liquid, solid and relatively hard for pre-delivery: See previously cited Fulton '883 for reference). Preissman goes on, disclosing that the material carries unitary pieces of metal or titanium forming a marker, the metal ranging in size up to 2.2mm (col. 2, II. 53-57; col. 4, II. 34-44). Preissman also discloses that the shape of the tracers is to be identifiable from bony landmarks at the tissue site (col. 4, II. 55-59). Preissman also discloses that the first material comprises PGA or PLA (col. 2, II. 36-52).

17. It would have been obvious to one of ordinary skill in the art to modify the tissue marking device and marker of Burney in view of the material composition of Preissman. The motivation to modify Burney in view of Priessman would have been to improve the visibility of a biodegradable material, as taught by Priessman.

18. Regarding claims 241, 248, While Preissman does not disclose that second component is shaped like a sphere, Preissman does not disclose that the second component is formed from any other shape than a sphere. Here, Preissman merely

states that the shape of the tracers is to be identifiable from bony landmarks at the tissue site (col. 4, ll. 55-59). The Examiner maintains that absent any further details one of ordinary skill in the art would recognize that providing a shape to tracers so that they are identifiable would include un-natural or distinguishable shapes including corners, flat shapes, squares as mere examples.

***Response to Arguments***

19. Applicant's arguments with respect to claims 237-264 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571)272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/LONG V. LE/  
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